Colorado
Office of Economic Development and International Trade




BIOSCIENCE DISCOVERY EVALUATION GRANT PROGRAM
For Proof of Concept Projects
2011-2012 Program
(RULES AND APPLICATION)

CONTENTS

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I. PROGRAM OVERVIEW

The Proof-of-Concept grants under the Bioscience Discovery Evaluation Grant Program (BDEGP) are intended to support bioscience discoveries that will likely lead to the development of new products, services, businesses and employment in the bioscience industry in Colorado. Grants of up to $150,000 are accessible to Offices of Technology Transfer (OTT) affiliated with qualified Colorado Research Institutions to enhance the commercial potential of bioscience research projects that focus on life sciences, engineering, material sciences, computer sciences, photonics, or nanotechnology.

II. APPLICATION AND REVIEW SCHEDULE

Eligible research institutions have either been grouped into a competitive pool, or have been allocated a portion of available grant funds, based on their relevant research activity. The *Grant Awards* section of this document has more information on the allocation of funds.

A. COMPETITIVE POOL APPLICANTS

OEDIT has established the following application deadline and review/decision schedule for applications under the competitive funding pool. Institutions identified as being eligible under the competitive pool are: Bonfils Blood Center, Colorado School of Mines, St. Mary's Hospital and Medical Center, University of Denver, and University of Northern Colorado.

OEDIT Application Deadline	**Grant Decisions**
First Cycle: **October 30, 2011**	**December 15, 2011**
Second Cycle: **April 30, 2012**	**June 15, 2012**

B. APPLICANTS WITH ALLOCATIONS

The OTTs for Research Institutions with set allocations (Colorado Initiative for Molecular Biotechnology, Colorado State University, National Jewish Health, and the University of Colorado) may establish their own grant cycles within the 2011-2012 state fiscal-year; however, they must submit applications committing at least fifty percent of their total allocation by December 1, 2011. Total grant funds requested by each institution may not exceed the allocations set-forth in the *Grant Awards, Allocation* section of this document. The Offices of Technology Transfer for these Research Institutions must submit an application schedule, and any application guidelines or processes unique to the institution, to OEDIT for review and approval before opening the application process to investigators.

C. SUBMISSIONS

An electronic copy of the application must be received by midnight MST on the deadline date. The application must also be submitted in paper-form, and must include an original signature on the certification page; the paper application may follow the electronic submission.

D. GRANT CYCLES

All funds are available for first cycle applicants; remaining funds will be available in a second cycle. Funds not awarded in these cycles will be available for Proof-of-Concept grants in the next fiscal year.

III. STATUTORY AUTHORITY

The Bioscience Discovery Evaluation Grant Program (BDEGP or Program), pursuant to C.R.S. 24-48.5-108 and 12-47.1-701, was established by the Colorado legislature to supply needed resources for improving and accelerating the evaluation process for bioscience research discoveries, to determine the best disposition of these discoveries, and to accelerate viable technologies toward commercialization. The legislature declared that it is in the best interests of the state's economic growth to dedicate financial resources to facilitate the development of new bioscience research discoveries in Colorado and promote Colorado-based bioscience technologies that will ultimately create new bioscience companies and additional primary jobs in Colorado.

IV. ELIGIBILITY

Proof-of-Concept grants are available to Offices of Technology Transfer at eligible Research Institutions for bioscience research projects that focus on life sciences, engineering, material sciences, computer sciences, photonics, or nanotechnology. Applicants must have matching funds that are at least equal to the amount applied for under the BDEG program. The scope of the bioscience project proposed should advance the commercial potential of the underlying technology.

Research Institution means an institution located and operating in Colorado that is a public or private, nonprofit institution of higher education, a nonprofit teaching hospital, or a private, nonprofit medical and research center. For-profit entities are not eligible for the Program.

Office of Technology Transfer means an office that is affiliated with a research institution and that is charged with the responsibility for technology transfer and that arranges for the sale or licensure of a bioscience research project to an outside entity, which is commonly a commercial enterprise.

Eligible Research Institutions with established Offices of Technology Transfer are:

Institution	Office	Contact	Phone	e-mail
Bonfils Blood Center	Technology Transfer	Daniel R. Ambruso, MD	303-341-4000	daniel_ambruso@bonfils.org
Colorado Initiative in Molecular Biotechnology	CU Technology Transfer Office	David Allen, PhD	303-735-3711	david.allen@cu.edu
Colorado School of Mines	Technology Transfer	Will Vaughan, PhD	303-384-2555	will.vaughan@is.mines.edu
Colorado State University	CSU Research Foundation Technology Transfer Office	Todd Headley	970-482-2916	todd.headley@colostate.edu
National Jewish Health	Technology Transfer Office	Emmanuel Hilaire, PhD	303-398-1262	hilairee@njhealth.org
St. Mary's Hospital and Medical Center	Western Slope Office of Technology Transfer	Mariah Zerbe	970-243-5242	mzerbe@gjincubator.org
University of Colorado (system-wide)	CU Technology Transfer Office	David Allen, PhD	303-735-3711	david.allen@cu.edu
University of Denver	Intellectual Property and Technology Transfer Office	Carley Pavelka	303-871-4230	cpavelka@du.edu
University of Northern Colorado	Graduate School & Technology Transfer	Robbyn R. Wacker, PhD	970-351-1582	robbyn.wacker@unco.edu

Bioscience Research means the study of biological processes, organisms, devices, diagnostics, or systems with the objective of developing products that are intended to improve agriculture, the quality of human life, or the environment. “Bioscience Research” includes, but is not limited to, biofuel research and life sciences research.

Biofuel Research means the use of microorganisms, specialized proteins, or thermal processes to develop biologically based fuel products from plant matter or other biological material, including renewable agricultural sources, and the related processes that make traditional manufacturing of energy cleaner and more efficient.

V. GRANT AWARDS

The Bioscience Discovery Evaluation Cash Fund has been established to hold monies and provide grant awards for the BDEGP. The Cash Fund is subject to state budget priorities and relies upon funds being appropriated, budgeted, and otherwise made available. The Cash Fund should provide $1,568,363for Proof-of-Concept Grants for fiscal year 2011-12 which includes new appropriations and funds carried-over from prior years.

A. ALLOCATION

A preliminary allocation of grant-funds has been made to eligible research institutions as follows:

Research Institution	FY 2011-12 Allocation
Bonfils Blood Center	235,254
Colorado School of Mines	
St Mary's Hospital and Medical Center	
University of Denver	
University of Northern Colorado	
Colorado Institute for Molecular Biology	299,557
Colorado State University	352,882
National Jewish Health	156,836
University of Colorado	523,833
TOTAL	$ 1,568,362

The amounts allocated will be available to the institutions for both the first and second grant cycles. These allocations may be adjusted to accommodate other qualified applicants, to incorporate new information on research activity at the research institutions, or as directed by the legislature or Office of State Planning and Budget.

In determining which research institution's pool of funds to draw from for grant awards, the employment/affiliation of the lead researcher and ownership of intellectual property will be taken into account. All grants will be awarded to OTTs at qualified Research Institutions who will distribute the grant to the specific approved project.

B. GRANT MAXIMUM

1. Proof-of-Concept projects can receive a maximum grant of $150,000.
2. The Bioscience Discovery Evaluation Grant Committee (BDEGC) may recommend a grant for an amount other than that requested in the application. Final decisions will be made by the Executive Director of OEDIT.

C. ELIGIBLE COSTS

Costs eligible to be paid under the program may only be incurred after the effective date of a legal agreement executed with OEDIT.

1. **Direct Costs** are related to specific time and effort and are readily and specifically identifiable with the bioscience research project. Direct costs include market analysis, qualified consultants (such as clinical consultants), analytical or laboratory work (such as prototype/product design, toxicology, manufacturability), documented direct time worked on project (such as investigator time), leased equipment, and direct lab supplies (consumables). Costs related to intellectual property (IP), Freedom to Operate analyses, travel expenses and equipment purchases are generally not eligible. Any other costs must be considered/approved on a case-by-case basis. Documentation of these expenses including invoices of actual expenses should be maintained. Total Direct Costs must be matched on a one-to-one basis.
2. **Indirect Costs**, also known as Indirect Cost Recovery or Facilities and Administrative, are those incurred for common or joint objectives. They are not readily and specifically identified with a specific bioscience research project. Indirect costs payable with grant funds are limited to 8% of the project's total direct costs. Any indirect costs to be paid with BDEGP funds must be charged to matching funds in at least the same amount. The OTT may utilize its negotiated federal rate for sponsored projects to support the indirect cost incurred, however, indirect costs exceeding 8% of total direct project costs will not reduce the required one-to-one match on Direct Costs.

D. MATCHING FUNDS

Applicants must have matching funds committed at the time of application. At least a 1:1 match of the grant requested is required. Both total Direct Costs and Indirect Costs must be matched on a 1:1 basis. By

project termination, matching funds must be expended on a 1:1 basis. Matching funds should not be spent prior to BDEGP project approval and execution of a grant agreement.

Generally matching funds are cash, but in-kind support may be allowed. When in-kind support is used to match the BDEGP grant, indirect costs must be documented and paid by the provider of matching funds, or by the research institution, or technology transfer office.

An OTT may use interest earned by the OTT on BDEGP funds to pay for eligible project costs; however, such interest is not considered matching funds.

E. PAYMENTS

Grantees will generally be compensated, on a pre-paid basis, for eligible costs projected for performance of the project plan. Grants to state institutions will be advanced in full, whereas 5% of the grant award to non-state awardees will be held until project completion and review of the final report. All advance payments are subject to approval by the State Controller's Office.

F. LEGAL AGREEMENTS WITH OEDIT

OTTs will need to have a Grant agreement executed with OEDIT prior to proceeding with any aspect of the bioscience research project including the expenditure of state and matching funds.

G. BUDGET ADJUSTMENTS

OEDIT acknowledges that the costs outlined in the Application budget are estimates. Therefore, a Grantee may adjust budget line-items up to 10% of the total budget – except that indirect costs may not exceed 8% of total direct costs – without approval from the state. The grantee will need to identify any budget shifts in its annual project reports. For larger shifts of funds between line-items, the grantee must first seek approval from OEDIT. Please see the sample budget in the Application section for an understanding of the budget layout.

H. RETURN OF UNUSED GRANT MONEY

Upon completion of a bioscience research project or within 60 days of early-termination of a project by the OTT's choice, any advanced and unused grant money, shall be returned by the OTT to OEDIT. The funds will be de-obligated and returned to the Bioscience Discovery Evaluation Cash Fund.

VI. APPLICATION REVIEW

Each institution that plans to submit an application must first conduct an internal OTT Review as described below. Applications meeting program guidelines and found to have strong commercial potential should be submitted to OEDIT. OEDIT will review all applications for compliance with the rules outlined in this document. Applications for the competitive pool of funds will also be evaluated by the Bioscience Discovery Evaluation Grant Committee.

A. OTT REVIEW

Each OTT shall develop an internal review and selection process for applications to be forwarded to OEDIT. The review shall place specific emphasis on improving and accelerating the evaluation process for bioscience research discoveries, to determine the best disposition of these discoveries, and accelerate viable technologies toward commercialization. The review should favor projects that can be expected to create new bioscience companies and additional primary jobs in Colorado. The OTT's internal review committee shall be comprised of OTT, research institution, and private bioscience industry representation. Documentation of this process must be submitted to OEDIT.

B. BDEGC REVIEW

1. OEDIT shall convene a Bioscience Discovery Evaluation Grant Committee (BDEGC) comprised of industry experts as well as Colorado Bioscience Association (CBSA) and OEDIT representatives to review, evaluate and make recommendations on applications for the competitive pool of funds. The competitive pool allocation within the Proof-of-Concept grant funds is available to those listed in the *Allocation* section of this document. All applications will be competitively evaluated by the BDEGC to focus on those that best advance the commercial potential of a bioscience discovery.

   Basic Evaluation Criteria

   Sound scientific basis

   Clear market potential

Manageable regulatory path
Use of funds will provide a significant return on investment advancement of the technology

2. The BDEGC operates on a consensus basis. Committee members bring various expertise to the process and rely on one another's input in making recommendations for further consideration and funding. Top applicants will be informed of the BDEGC meeting at which their proposal will be further considered, and are encouraged to attend.
3. OEDIT staff will provide constructive feedback to applicants from the BDEGC as available. Applicant's questions on the review process or feedback should be directed to OEDIT staff. BDEGC members will not discuss committee deliberations with applicants, but may choose to give personal advice.

VII. CONFIDENTIALITY AND OPEN RECORDS

OEDIT is subject to the Colorado Open Records laws (C.R.S. 24-72-101 through 24-72-112). Thus, documents and other materials received by OEDIT and its employees may be subject to public disclosure.

OEDIT will deny the right of inspection of records considered trade secrets, privileged information, and confidential commercial and financial data. Applicants should clearly mark areas of the application they consider to be trade secrets, privileged information, and confidential commercial and financial data. **The entire application may not be marked "confidential".** Please note that information considered confidential at the time of application may cease to be so at a later date.

Upon receiving an official open records request, OEDIT will immediately notify the applicant and as needed, seek legal guidance from the Office of the Attorney General for a ruling on confidential information. Applicants should be aware that OEDIT can only respond to requests to review records to the extent that such information is contained in OEDIT's files.

The applicant should also be aware that the Bioscience Discovery Evaluation Grant Committee (BDEGC), most of who are not state employees, will receive and review the application documents. Committee members have agreed to lend their expertise and advice in reviewing grant applications, solely to benefit the public. Panel members agree to treat applications and panel discussions as confidential.

VIII. REPORTING REQUIREMENTS

A. ANNUAL PROGRESS REPORT

1. For each project receiving grant funds, the OTT must submit an annual report documenting the progress of the research and commercialization activity. This report tracks accomplishments related to the objective, obligations and budget developed for each project in the Statement of Work in the Grant Agreement. OTTs will report on results achieved, monetary and other returns associated with licensing the technology, companies and jobs created. The report will need to identify the use of grant and matching funds. A project financial report must be included. A report outline is available from OEDIT. The OTT must complete and return annual reports to OEDIT by March 15th in the same electronic format that the report outline was given. If additional supporting documentation (such as expense receipts) is not available in an electronic format, a hard-copy of the full report and supporting materials should be submitted to OEDIT in addition to the electronic copy of the report.
2. Additionally, the OTT's annual report must include information associated with completed projects that received BDEGP grant funds. The following information must be included in the annual report to assist the state in evaluating the success of the state program in fostering development of Colorado's bioscience industry:
    - Name of project, grant name, grant date, grant amount, total cost of project
    - Status of IP – Was new IP developed? Has the IP been extended or obligated outside of the OTT or Research Institution? If so, provide details.
    - Technology Licensing – Has the technology been licensed outside of the RI? To whom?
    - Follow-on Capital Investment – Since the conclusion of the state Grant Award, what capital investment has this technology received?

B. EDUCATION PRESENTATION

At some point during the grant period, the grant recipient must present the research project to elementary and secondary school science teachers employed in the geographic region in which the technology is being developed – generally, this could be in the local school district. If a researcher does not already have

school contacts, CBSA may be able to provide some. The aim of this requirement is to provide relevant and interesting examples of scientific discovery and applied research for teachers and students. The format of the required presentation is not set, and the grantee or researcher may develop his or her own creative approach to fulfilling this requirement. OEDIT's Bioscience Program Manager should be informed in advance of the presentation, and may attend any presentations. The grantee must report to OEDIT on its performance of this requirement upon fulfillment either in an Annual Progress Report or the Project End Report.

C. PROJECT FINAL REPORT

This report is a similar format to the annual report, but is provided at the conclusion of a project/grant. The end report should document completion of all activities outlined in the Statement of Work. This report should include an analysis of the results and findings from the project efforts. Technical difficulties, errors, and planned or recommended next steps should be described. A project financial report identifying matching and grant funds must be included. An outline for this report is available from OEDIT, and is the same as that for the Annual Report. The final report will be due to OEDIT not later than 30 days before the expiration or sooner termination of a grant (and as identified in the formal Grant Agreement).

IX. AUDITS

A. OTT

Each OTT will be required to provide a copy of any OTT or Research Institution (RI) annual audit released during the term of the Agreement to OEDIT. For most OTTs, this requirement will mean a copy of the research institutions audit. For OTT's that are legally separate but affiliated with a research institution, the OTT will need to provide a copy of their annual audit.

B. PROJECT

The project itself, including the primary researcher and laboratory or research setting are subject to monitoring and audit for performance under a grant agreement. A grantee shall maintain a complete file of all records, documents, communications, notes and other written materials or electronic media, files or communications, which pertain in any manner to the operation of programs or activities undertaken pursuant to an executed Agreement. Such books and records shall contain documentation of the participant's pertinent activity under a Grant Agreement in a form consistent with good accounting practice. An Audit Checklist is available from OEDIT.

X. APPLICATION

To be eligible for a grant under the program, Offices of Technology Transfer shall submit to OEDIT (see contact information on page 1) **one original signed hard-copy** application, **and by e-mail a Word file**, for each bioscience research project. Such application(s) shall be submitted on or before the OEDIT Application Deadline (see page 2) in order to be considered in an application cycle.

The application should follow this format. Please address each statement and answer every question. Presentation and writing are evaluated in the review of the application. Incomplete Applications may not be considered.

A. IDENTIFYING INFORMATION

1. Name of Office of Technology Transfer & Associated Research Institution
2. Contact Information for OTT (name, phone #, e-mail address)
3. Identify which OTT or Research Institution(s) owns the subject intellectual property
4. Title of specific Bioscience Research Project
5. Primary Investigator (name, phone #, e-mail address)
6. Identify the Research Institution(s) that employs the Primary Investigator
7. Has this scientist received any other BDEGP grant? If so, give the BDEGP project name, dates, and award amount.
8. Check the box(es) that describe the field to which the project proposal relates
   - ❑ Human Health - therapeutic or diagnostic products, devices or instruments
   - ❑ Agriculture – bioscience technologies that improve agriculture
   - ❑ Biofuels – development of biologically based fuels

9. Requested State Grant Amount (not to exceed $150,000, this figure should not include matching funds)
10. Anticipated Grant Term (anticipate agreements to be executed within 60 days of Grant Notification date)
11. Submit a signed W-9 form and a Certificate of Good Standing from the CO Secretary of State for the applicant OTT.

B. PROJECT NARRATIVE

1. Summary *(1 page or less in **layman's terms**, do not include confidential information)*
   Provide a brief summary of the proposed Project including:
   - a description of the commercialization plan,
   - the scientific research and its merits,
   - anticipated commercial potential of the technology being developed,
   - the market segment that the developed technology will address.
     Will this product/service be a new offering? Does it improve upon existing offerings? Will it partner with existing products/services?

2. Project Plan *(3 pages or less in layman's terms)*
   a) Describe the specific objectives of the project *(in 70 words or less). If approved, this language will become the general description in a Statement of Work.*
   b) Articulate key objectives and specific aims of the project.
   c) Describe the commercialization spectrum (from infancy to sales) explaining where the technology is today, and how far along the spectrum it will progress by completing the work you plan to undertake with the state grant and matching funds.
   d) Identify the technical questions that will be addressed by any research conducted as part of the project, and explain how addressing those questions will enhance the commercial potential of the technology.
   e) Describe the approach to the research, major elements of research design, and key features of the methodology.
   f) Describe how the proposed project builds upon previous research that has been conducted by the applicant research institution and other institutions worldwide.
   g) Identify problems that you might encounter in the proposed project and how you intend to manage and/or resolve them.

3. Commercialization *(2 pages or less in layman's terms)*
   a) Describe the anticipated market potential for the product or service that will ultimately be developed as a result of this project. How will the product positively impact human health, agriculture, or biofuels offerings?
   b) Identify the strengths, weaknesses, opportunities and threats of this technology in meeting a market need.
   c) Identify any developed intellectual property to-date on this research.
   d) Is the IP obligated outside of the Research Institution or OTT? If so, to whom?
   e) Estimate the long-term outcomes of this project in terms of Colorado jobs and investment.

4. Hazardous Substances
   Will project work involve hazardous substances or activities? If so, what precautions are being taken. Note laws that apply, additional insurance, etc.

5. Work Performance Location
   Where will project work, including any subcontracts, be performed? List each country and state where work will be performed, and describe the type of work that will be performed at each location.

   If it is anticipated that services under the contract, or any subcontracts, will be performed outside of the United States or the State of Colorado, explain why it is necessary or advantageous to go outside the United States or the State of Colorado to perform the contract or any subcontracts.

C. WORK PLAN

Drawing on the Project Narrative, identify specific project tasks/milestones on a timeline (and tie them to a budget where feasible). *Please be concise as these will become the "Obligations" in a Statement of Work.*

Make sure to identify project start and end dates in terms of months from an executed Grant Agreement. Be aware that it may take up to 60 days following the grant decision date to process follow-on information and execute a Grant Agreement.

D. BUDGET

1. Has the subject technology of this application received other grant funding? If so, please provide grant source, amount, and scope of grant project.

2. Provide a project budget that supports the Work Plan above. Refer to the *Eligible Costs* and *Matching Funds* information in the *Grant Awards* section of this document. The budget should include all anticipated project costs and identify Program grant and matching funds. This sample budget outline is provided for direction. Please include a re*asonable leve*l of detail for plan*ned project* expenditures. Matching funds for Direct Costs may be applied to different line-items than BDEGP funds, but should develop the same technology and be spent over the same time period.

Line Item		Source		Total
Direct Costs		BDEGP	Match	
	Personnel & Labor	25,000	26,000	51,000
	Tuition Remission	5,000	5,000	10,000
	Materials & Supplies	16,000	5,000	21,000
	Publication Cost	2,500	2,500	5,000
	Equipment Rental Fees	10,000	20,000	30,000
	Field Trials	4,000	4,000	8,000
	Service Contracts	16,000	16,000	32,000
Total Direct		78,500	78,500	157,000
Indirect Costs		6,280	31,400	37,680
TOTAL		$84,780	$109,900	$194,680

3. Provide budget justification based on line-items included in your budget.

   a) Where Personnel costs are included, indicate: job title(s), project responsibility(ies), hourly rate (including benefits), and estimated hours.
   b) Where Consultants/Subcontractors are needed, indicate project responsibility(ies), hourly rate, and estimated hours.
   c) Where Supplies are needed, list item(s), price and purpose.
   d) For all Other line items, provide detail as appropriate.
   e) Where Indirect Costs are budgeted, indicate who will receive these funds and for what purpose.

E. RESEARCHERS' BIOGRAPHICAL INFORMATION

Please attach curriculum vitae or a short narrative with relevant background and accomplishments for each of the key investigators and project developers.

F. EDUCATIONAL OUTREACH

Describe your preliminary plans for fulfilling educational outreach to science teachers in your school district. See the Reporting Requirements section for information on this requirement.

G. OTT PROCESS *(please limit to 2 pages)*

1. Application/Review Process. Describe or attach the OTT's process for application, review and selection including the committee decision-making process, and a list of the people and their functions that participated throughout the OTT review/approval process for this specific bioscience research project.

2. Provide a description of the OTT's conflict of interest policies/processes (either briefly describe or attach). Disclose any real or perceived conflicts of interest related to this specific bioscience research project.

*note: Should the OTT Review Process and/or the Conflict of Interest Policy be the same, the OTT need submit these documents only once for multiple project applications in a grant cycle. However, the applicant should be sure to make any disclosure related to conflict of interest for each project.

XI. CERTIFICATIONS

The OTT certifies that:

- The bioscience research project described in this application and for which the OTT is requesting Program funds complies with the statutory criteria, rules and application requirements identified in this application document:
  - the bioscience research involves the use of biological processes, organisms, devices, diagnostics, or systems with the objective of developing products that are intended to improve agriculture, the quality of human life, or the environment;
  - the scope of the project is the scope required to enhance the commercialization of the technology in Colorado;

- The OTT has a dedicated, matching source of moneys that is equal to or greater than the amount applied for under the program.

- The information contained in this Application, including all attachments and exhibits, are true and correct.

- The person's or persons' signature on these Certifications and Application are authorized to act on behalf of the OTT.

_____	_____
Name and Title	Name of OTT
_____	_____
Signature	Date

OEDIT reserves the right to modify any of the rules here-in, so long as such modifications meet statutory criteria. Interested parties will be notified of any such modification.